INNOVATIVE BIOCERAMIX INC.
1628 West 75th Avenue
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Tel: 604-221-6800
Fax: 604-677-6129

K082943

1 of 2

510(k) SUMMARY

JAN - 6 2009

This summary of 510(k) is being submitted in accordance with 21 CFR 807.92

SUBMITTER: Innovative BioCeramix Inc.
1628 West 75th Avenue
Vancouver, BC
V6P 6G2 Canada
Tel: 604-221-6800 Fax: 604-677-6129

CONTACT: Quanzu Yang

SUMMARY PREPARED: September 26, 2008

TRADE NAME: iRoot BP

COMMON NAME: Injectable Root Canal Repair Filling Material

CLASSIFICATION NAME: Resin, Root Canal Filling (21 CFR 872.3820, Product Code: KIF)

PREDICATE DEVICES:

- BioAggregate (K063422)

Specific chemical compositions:

- BioAggregate (K063422)
- iRoot SP (K080917)
- Jeltrate® Plus™ Impression Material (K952614)
- Clearfil™ Ceramic Primer (K061906)

Delivery system:

- iRoot SP (K080917)

DEVICE DESCRIPTION: iRoot BP Injectable Root Canal Repair Filling Material (iRoot BP) is a convenient ready-to-use white hydraulic premixed injectable BioAggregate paste developed for permanent root canal repair and filling applications. iRoot BP is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. iRoot BP does not shrink during setting and demonstrates excellent physical properties. iRoot BP is packaged in a preloaded syringe and is supplied with disposable tips.

INTENDED USE:

- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification
- Pulp Capping

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2872

TECHNOLOGICAL CHARACTERISTICS:

iRoot BP and BioAggregate are designated for the equivalent dental applications, and have comparable chemical and physical properties, and performance specifications.

The main chemical composition of iRoot BP is based on BioAggregate. Additional predicate devices include: iRoot SP, Jeltrate® Plus™ Impression Material and Clearfil™ Ceramic Primer, each contains specific chemical components that are equivalent to those found in iRoot BP; providing evidence that these chemical components are safe and effective for medical device use. Furthermore, iRoot BP and iRoot SP have similar delivery systems.

NON-CLINICAL TESTS PERFORMED:

iRoot BP has undergone extensive bench and biocompatibility testing to provide evidence that iRoot BP's chemical and physical properties are substantially equivalent to BioAggregate and iRoot SP. Bench tests included: flow, working time, setting time, dimensional change following setting, solubility, and radiopacity.

Biocompatibility test results determined that iRoot BP is non-cytotoxic. Since iRoot BP's chemical composition is based on the principal chemical components in both BioAggregate and iRoot SP, the biocompatibility test data of BioAggregate and iRoot SP provides biocompatibility evidence that iRoot BP is non-mutagenic, does not cause an allergenic potential after multiple uses and has a good tolerance by subcutaneous tissue.

CONCLUSIONS:

iRoot BP has the same indications for use, provides similar chemical, physical and biocompatible properties, and demonstrates comparable performance specifications to BioAggregate. iRoot BP's main chemical composition is based on BioAggregate and the additional chemical components in iRoot BP's composition were found to be safe and effective in iRoot SP, Jeltrate® Plus™ Impression Material and Clearfil™ Ceramic Primer. In addition, iRoot BP has a comparable delivery system to iRoot SP. Therefore, it is concluded that iRoot BP is safe, effective and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 6 2009

Mr. Quanzu Yang
President/ Chief Executive Office
Innovative BioCeramix, Incorporated
1628 West 75th Avenue
Vancouver, BC
V6P 6G2 Canada

Re: K082943
Trade/Device Name: iRoot BP Injectable Root Canal Repair Filling Material
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: December 12, 2008
Received: December 29, 2008

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, MD
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1071

INDICATIONS FOR USE

510(k) Number (if Known): K082943

Device Name: iRoot BP Injectable Root Canal Repair Filling Material

Indications for Use:

- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification
- Pulp Capping

Prescription Use √ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sally Y. Michaud D.M.D.

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082943